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Attorney Docket 8465/40

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Lasse W. Mogensen, et al.	:	
		:	
Serial No.:	10/687,568	:	Confirmation No.: 7139
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Filed:	October 15, 2003	:	Group Art Unit: 3767
		:	
For:	INJECTOR DEVICE FOR PLACING A	:	Examiner: Elizabeth MacNeill
	SUBCUTANEOUS INFUSION SET	:	

**BRIEF ON APPEAL TO THE
BOARD OF PATENT APPEALS AND INTERFERENCES**

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Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Unomedical A/S pursuant to an assignment that was recorded at Reel 015221, Frame 0933.

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(3) RELATED APPEALS AND INTERFERENCES

Appellant calls the Board's attention to two related appeals.

On August 26, 2008, a Notice of Appeal was filed for the presently-appealed United States Patent Application Serial No. 10/687,568 ("the '568 Application"). The '568 Application was filed on October 15, 2003 as a continuation-in-part of PCT/DK02/00640 filed on September 27, 2002, which is continuation-in-part of United States Patent Application Serial No. 09/995,237 filed on November 26, 2001, now Patent No. 6,830,562, which is a continuation-in-part of United States Patent Application Serial No. 09/967,400 filed on September 28, 2001, now abandoned.

Also on August 26, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 10/813,214 ("the '214 Application"). The '214 Application was filed on March 29, 2004, as a continuation of the '568 Application discussed above.

On October 3, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 11/031,635 ("the '635 Application."). The '635 Application was filed on January 7, 2005 as a continuation of the '568 Application discussed above. The Brief on Appeal for the '635 Application is neither due nor filed as of the filing of the Appeal Brief that is the subject of the present appeal.

Accordingly, the '214 Application and the '635 Application are being simultaneously appealed to the Board of Patent Appeals and Interferences together with the '568 Application that is the subject of the present appeal. Decisions in the '214 Application and/or the '635 Application may directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal. To date, no decision has been rendered by a court or the Board in the appeals of the '214 Application and the '635 Application.

The undersigned is unaware of any other prior or pending appeal, interference, or judicial proceedings that may be related to, directly affect or be affected by, or have a bearing on the Board's decision in this Appeal.

(4) STATUS OF CLAIMS

The claims presented are Claims 40–43 and 50–73. The following claims have been allowed: 40–43, 50–54, 67 and 68. The Examiner did not address (by way of rejection, objection, or allowance) Dependent Claim 65, which depends from an allowed base claim 42. The Examiner rejected Dependent Claim 73, but without reading it on any reference or even citing a reference in reaching the rejection. The Examiner rejected claims 55, 57, 60, 66, 70–72 under 35 U.S.C. § 102(b). The Examiner rejected claims 55–57, 60–64, 66, and 69–72 under 35 U.S.C. § 102(e). Claims 58 and 59 were rejected under 35 U.S.C. § 103(a). All rejected claims are appealed.

(5) STATUS OF AMENDMENTS

Prior to the filing of the present Brief on Appeal to the Board of Patent Appeals and Interferences, no amendments were filed in response to a final Office Action dated May 23, 2008. Hence there is no un-entered amendment. Accordingly, Claims 40–43 and 50–73 are pending. Claims 55–64, 66, and 70–73 are rejected and appealed. Claim 65 was not allowed, objected, or rejected, and is appealed. A copy of all claims, omitting status indicators, appears in the Claims Appendix, pages 30–36.

(6) SUMMARY OF CLAIMED SUBJECT MATTER

In the Claims filed April 23, 2008, and now appealed, Claims 55, 56, 58, 61, 66, and 67 are independent, and Claims 57, 59–60, 62–65, and 69–73 are dependent. Below, Appellant provides brief descriptions of, reciting pages and line numbers and drawing reference numerals for, each of the Claims on Appeal. Please note that, in the brief description that follows, like elements will utilize reference numerals from the various embodiments of the claimed inventions.

(a) Independent Claim 55 and Dependent Claims 57, 60, and 73.

Independent Claim 55 describes one aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (**28, 128, 228, 328**) as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for movement between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(4) a lock (**34, 134**) for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger. A lock is shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24. A lock is discussed at least in ¶¶ 46 and 51. Release of the plunger is caused by for example, pressing manually on diametrically opposed outside areas (**303**) of the device housing to deform the housing and thereby effect release of trigger arms (**38**) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(5) a drive for urging said plunger from the retracted position toward said advanced position as shown in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12. A drive is discussed at least in ¶¶ 43, 46, 54, 61, and 70–74. In one embodiment, the drive comprises a spring (**36, 136, 236, 336**) as shown for example, in the foregoing figures and paragraphs.

Claim 57 depends from Independent Claim 55 and further recites that the device housing has a forward end defining a generally planar surface (**25**) for placement against the

skin of a patient with the device housing in a predetermined orientation relative to the patient's skin. This is shown in Figures 1–12 and discussed in ¶¶ 44, 47, 51, and 55–56.

Claim 60 depends from Independent Claim 55 and further recites a removable cover (142, 342) covering said infusion set and a hollow portion for receiving a part of an insertion needle (12, 112, 212, 312) when said plunger is in said advanced position. The cover is shown in at least Figures 6, 11, and 19, and is discussed at least in ¶ 67. The needle is shown in Figures 1–4, 6–11, 15–16, 18–19, 20b, 20e, 21b, and 23b, and is discussed at least in ¶¶ 38–44, 46–49, 52, 54–57, 61–65, 67–69, 76, and 78.

Claim 73 depends from Independent Claim 55 and further recites that said housing comprises a pair of manual engagement areas (303), said manual engagement areas being pressed radially inwardly in said second geometrical configuration. Release of the plunger is caused by pressing manually on the diametrically opposed engagement areas of the device housing to deform the housing and thereby effect release of trigger arms (38) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(b) Independent Claim 56.

Independent Claim 56 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including a housing (14, 114, 214, 314) and a hollow cannula (26, 126, 226) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (28, 128, 228, 328) as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a cover member (142, 342) removably secured to said device housing, said cover member covering an end of said device housing. A cover

member is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, and 67.

(4) a molded plunger (30, 130, 230, 330) movably received within said device housing for movement between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(5) a lock (34, 134) for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger. A lock is shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24. A lock is discussed at least in ¶¶ 46 and 51. Release of the plunger is caused for example, by pressing manually on diametrically opposed outside areas (303) of the device housing to deform the housing and thereby effect release of trigger arms (38) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(6) a drive for urging said plunger from the retracted position toward said advanced position as shown in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12. A drive is discussed at least in ¶¶ 43, 46, 54, 61, and 70–74. In one exemplary embodiment, the drive comprises a spring (36, 136, 236, 336) as shown in the foregoing figures and paragraphs.

(7) wherein said device housing includes a space for accommodating a tubing (113) that forms part of said infusion set for delivery of medication to said hollow cannula as shown in Figures 8–11, 17–18, and 23a–23b and as discussed at least in ¶¶ 44, 52, 55, 64–65, 69, and 77–78.

(c) Independent Claim 58 and Dependent Claim 59.

Independent Claim 58 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (**28, 128, 228, 328**) as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a cover member (**142, 342**) removably secured to said device housing, said cover member covering an end of said device housing. A cover member is shown for example in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, and 67.

(4) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for movement between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(5) a lock (**34, 134**) for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger. A lock is shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24. A lock is discussed at least in ¶¶ 46 and 51. Release of the plunger is caused for example, by pressing manually on diametrically opposed outside areas (**303**) of the device housing to deform the housing and thereby effect release of trigger arms (**38**) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(6) a drive for urging said plunger from the retracted position toward said advanced position as shown for example in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12. A drive is discussed at least in ¶¶ 43, 46,

54, 61, and 70–74. In one embodiment, the drive comprises a spring (**36, 136, 236, 336**) as shown in the foregoing figures and paragraphs.

(7) indicia relating to the shelf life of said assembly on said cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member. For this purpose, at least one of the covers, such as an upper cover (**194**) as shown in Figures 6–7, may carry printed indicia relating to the shelf life of the assembly. Indicia are discussed at least in ¶ 57.

Claim 59 depends from Independent Claim 58 and further recites the plunger being in said advanced position prior to first-time removal of said at least one cover member as shown for example in Figures 3, 6, 7, 12, 15, 20a, and 20b, and as discussed in ¶¶ 14, 23, 26, and 31.

(d) Independent Claim 61 and Dependent Claims 62–64.

Independent Claim 61 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (**28, 128, 228, 328**) as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a cover member (**142, 342**) removably secured to said device housing, said cover member covering an end of said device housing. A cover member is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, and 67.

(4) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for movement between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in

Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(5) a lock (34, 134) for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger. A lock is shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24. A lock is discussed at least in ¶¶ 46 and 51. Release of the plunger is caused for example, by pressing manually on diametrically opposed outside areas (303) of the device housing to deform the housing and thereby effect release of trigger arms (38) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

(6) a drive for urging said plunger from the retracted position toward said advanced position, said plunger having an insertion needle secured thereto by a stable connection preventing loss of said insertion needle (12, 112, 212, 312) during use of said injector device, said insertion needle extending through said cannula with the cannula oriented for transcutaneous placement upon movement of the plunger from the retracted position to the advanced position, said insertion needle secured to said plunger being removable from said cannula while maintaining the transcutaneous placement of the cannula. A drive is shown, for example, in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12, and is discussed at least in ¶¶ 43, 46, 54, 61, and 70–74. In one embodiment, the drive comprises a spring (36, 136, 236, 336) as shown in the foregoing figures and paragraphs. An insertion needle is shown in Figures 1–4, 6–11, 15–16, 18–19, 20b, 20e, 21b, and 23b, and is discussed throughout the specification, including ¶¶ 38–44, 46–49, 52, 54–57, 61–65, 67–69, 76, and 78.

Claim 62 depends from Independent Claim 61 and further recites the insertion needle being in frictional engagement with said infusion set as shown in Figures 18 and 23b, as well as in Figures 1–2 and 6–10, and as discussed at least in ¶¶ 43, 61, and 69.

Claim 63 depends from Independent Claim 61 and further recites the insertion needle being secured to said plunger by press-fit as shown in Figures 3, 6, and 19, and as discussed at least in ¶¶ 43, 52, 67, and 76.

Claim 64 depends from Independent Claim 61 and further recites the insertion needle being hollow and having an entry port (1') and an exit port as shown in Figures 23a and 23b and as discussed at least in ¶ 78.

(e) Independent Claim 66 and Dependent Claims 69–73.

Independent Claim 66 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including at least a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (**28, 128, 228, 328**) receiving at least a part of said infusion set, said part of said infusion set positioned removably from and within said device housing. A molded device housing is shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74. The molded device housing is shown positioned removably from and within said infusion set in Figures 1–2, 11, and 19, as well as in Figures 6–10, and as discussed at least in ¶¶ 43, 56, and 61.

(3) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(4) a lock (**34, 134**) for releasably locking said plunger in said retracted position as shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24, and as discussed at least in ¶¶ 46 and 51.

(5) a drive including a spring (**36, 136, 236, 336**) for urging the plunger from the retracted position toward the advanced position as shown in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12. A drive is discussed at least in ¶¶ 43, 46, 54, 61, and 70–74.

(6) a cover (**142, 342**) removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing as shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and as discussed at least in ¶¶ 51, 55–57, and 67.

Claim 69 depends from Independent Claim 66 and further recites a medical insertion needle (**12, 112, 212, 312**) substantially non-detachably attached to said plunger, said medical insertion needle extending through said cannula. The needle arrangement is shown in Figures 1–4, 6–11, 15–16, 18–19, 20b, 20e, 21b, and 23b, and is discussed at least in ¶¶ 38–44, 46–49, 52, 54–57, 61–65, 67–69, 76, and 78.

Claim 70 depends from Independent Claim 66 and further recites the device housing being manually deformable to effect release of said plunger. The manually deformable housing releases trigger arms (**38**) that had locked the plunger into a retracted position is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

Claim 71 depends from Claim 70 and further recites that the molded device housing comprises manual engagement areas (**303**). Release of the plunger is caused by pressing manually on diametrically opposed outside areas (**303**) of the device housing to deform the housing and thereby effect release of trigger arms (**38**) that had locked the plunger into a retracted position. This is shown at least in Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the specification, including at least in ¶¶ 43, 55, 68, and 72.

Claim 72 depends from Independent Claim 70 and further recites that injector device assembly of claim 66, wherein said cover comprises a hollow portion as shown at least in Figures 1–5 and as discussed in ¶¶ 44, 51.

(f) Independent Claim 67.

Independent Claim 67 describes another aspect of the invention. Briefly stated, an injector device assembly includes:

(1) an infusion set including at least a housing (**14, 114, 214, 314**) and a hollow cannula (**26, 126, 226**) as shown in at least Figures 17–18, 23a–23b, and 24, as well as in Figures 1, 6–11, and 14–16. An infusion set is discussed at least in ¶¶ 37, 39, 43–49, 52, 55–58, 61, 63–65, 69, and 76–77.

(2) a molded device housing (**28, 128, 228, 328**) receiving at least a part of said infusion set as shown in at least Figures 1, 6, 13, and 19–22b, as well as in Figures 2–5, 7–11, and 14–16. A molded device housing is discussed throughout the specification, including at least in ¶¶ 38, 43–46, 49, 51–57, 59, 61, 67–69, 71–72, and 74.

(3) a molded plunger (**30, 130, 230, 330**) movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position as shown in at least Figures 1, 5–6, 12, 14–16, 19–22b, and 24, as well as in Figures 2–4 and 7–11. A molded plunger is discussed throughout the specification, including at least in ¶¶ 38, 42–44, 46, 48, 51–55, 61–62, 67–74, and 79.

(4) a lock (**34, 134**) for releasably locking said plunger in said retracted position as shown in at least Figures 2 and 6, as well as in Figures 1, 3–5, 7–11, 19, 20c–22b, and 24, and as discussed at least in ¶¶ 46 and 51.

(5) a drive including a spring (**36, 236, 336**) for urging the plunger from the retracted position toward the advanced position, wherein said drive comprises a plurality of individual flexible plastics members (**136, 336A, 336B**), each member connected with the plunger and with the device housing as shown in Figures 2, 6–7, 12, 14–16, 19, and 20a–22b, as well as in Figures 1 and 6–12. A drive is discussed at least in ¶¶ 43, 46, 54, 61, and 70–74. The flexible plastics members are discussed in ¶¶ 70–73 and is further described as being connected to the plunger and device housing as shown in Figures 7, 12, 19, 20a–20d, and 21a–21d.

(6) a cover (142, 342) removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing, said cover receiving a part of said infusion set. A cover member is shown in at least Figures 6–8, 11, and 19, as well as in Figures 9–10, and is discussed at least in ¶¶ 51, 55–57, and 67. The cover is further shown receiving a part of said infusion set in Figures 6, 7, and 11, as well as in Figures 1–2.

(7) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There following grounds of rejection are presented for review:

(a) Claims 55, 57, 60, 66, 70–72 are rejected as anticipated by Miskinyar, U.S. Patent No. 4,894,054, under 35 U.S.C. § 102(b).

(b) Claims 55–57, 60–64, 66, and 69–72 are rejected as anticipated by Safabash et al., U.S. Patent No. 6,293,925, under 35 U.S.C. § 102(e).

(c) Claims 58 and 59 are rejected as obvious over Safabash et al., U.S. Patent No. 6,293,925, in view of Teeple, Jr., U.S. Patent No. 5,807,316, under 35 USC 103(a).

(d) Claim 65, which depends from an allowed base claim 42, is neither rejected nor objected to. However, claim 65 was not allowed.

(e) Claim 73, which depends from Independent Claim 55, is rejected. However, the Examiner did not provide a basis for the rejection of Dependent Claim 73, did not read the claim on any reference, and did not cite a reference in rejecting the claim.

(8) ARGUMENT

There are two steps to determining whether a claim is either anticipated under 35 U.S.C. §§ 102(b)–(e) or obvious under 35 U.S.C. § 103(a). First, the Board determines whether the Examiner properly interpreted the claim language. See *In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990). As shown below, the Examiner did not give the claims a *reasonable* interpretation. Second, for anticipation to exist, each and every limitation in the properly construed claims must be found in the prior art reference – exactly as claimed. *In re Bond*, 910 F.2d at 832. Likewise, to support a *prima facie* conclusion of obviousness, “all

claim limitations” must be found in the properly construed claims. *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994). As shown below, many claim limitations (when properly construed) do not read on the prior art.

- (a) **The rejection of claims 55, 57, 60, 66, and 70–72, as anticipated by Miskinyar should be reversed, because Miskinyar does not teach an “infusion set,” a “housing being manually deformable ... to effect release of said plunger,” or a “cover removably connected to a front end portion of said housing and ... receiving a part of said infusion set”**

Independent Claim 55 and dependent Claims 57 and 60 are rejected as anticipated by Miskinyar, U.S. Patent No. 4,894,054 (“Miskinyar”), under 35 U.S.C. § 102(b). For Miskinyar to anticipate the claims, every limitation recited in these claims must be present in the Miskinyar patent, but they are not.

(i) Miskinyar does not teach an “infusion set”

An “infusion set,” according to the specification, is used to infuse medical fluids such as insulin to a patient and generally includes a housing with an internal chamber (not shown) that receives medication via infusion tubing. The infusion set is mounted on the injector device for transcutaneous insertion of the cannula. After transcutaneous placement of the cannula, the injector device is retracted from the infusion set that is left on the skin for delivery of medication therethrough. (¶ 39)

The Examiner has incorrectly relied on Miskinyar, aptly titled a “Preloaded Automatic Disposable Syringe,” i.e., an inoculator. An inoculator has no separable component mounted in the device housing, let alone an infusion set removably mounted in the device housing. The syringe in Miskinyar is preloaded with a precisely measured dosage of medication for the patient. See Miskinyar, col. 3, l. 67 through col. 4, l. 2.

(1) Unintended Purposes

Does cutting off a needle and leaving the needle in a patient’s skin while the remainder of the syringe is removed sound like a good idea? Obviously not. Indeed, it might be acceptable practice in the medical field to use a needle to penetrate epidermis to inoculate a patient, but inserting a needle, cutting it off, and leaving it in the patient would not be safe, sanitary, or intended.

Yet, that is what the Examiner suggests when she modifies Miskinyar in an effort to anticipate the claimed infusion set having a housing and cannula. Nowhere does Miskinyar teach that its needle is intended to be cut from the syringe. However, the Examiner alters the intended purpose of the needle 22 of Miskinyar “by cutting” it from the housing. Advisory Action dated 8/14/2008, at 3. According to the Examiner, since the needle 22 can be cut, it is “capable of being removed and thus is ‘removable.’” *Id.* This is completely unrealistic and unreasonable.

The Examiner is creating a new theory of “possible” anticipation, whereby the possibility of changing prior art—even from its intended purpose—can be used to establish identity. MANUAL OF PATENT EXAMINING PROCEDURE § 2131, at 2100-76 (8th ed. 2006) (To anticipate a claim, the “identical invention must be shown.”). The Examiner cannot cite to any case where a reference had been modified from its intended purpose in order to prove anticipation. To the contrary, the term “anticipation” now carries a narrower meaning with Congress’ passage of the Patent Statute of 1952. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (“Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. . . . That which would *literally* infringe if later in time anticipates if earlier.”) (emphasis in original). Under the current patent statute, any differences from a prior art reference are not anticipatory but, instead, can only be analyzed for obviousness, if at all. Even then, a proposed modification must be for an “intended purpose.” MPEP § 2143.01, at 2100-137 (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”). It is respectfully submitted that cutting off a needle in a patient would be unsafe, unsanitary, and unintended.

(2) Plain Meaning

Also, the Examiner is not giving proper consideration either to the plain meaning of the claim terms or to the Appellant’s specification. First, the terms used in a claim are to be given their “ordinary and customary meaning.” *Phillips v. Awh Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Second, the claim term is to be read in view of the entire application,

“including the specification.” *Id.* at 1313. Indeed, the specification “‘is always highly relevant to the claim construction’ as it is ‘the best tool for determining the meaning of a claim term.’” *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). When given their plain meaning in light of the specification, the claimed inventions are patentably distinguishable from Miskinyar.

In contrast to the preloaded syringe of Miskinyar, Appellant developed an injector device for placing a subcutaneous infusion set on a patient. Improper needle placement is common for patients who are “reluctant or hesitant to pierce their own skin with a medical needle, and thus encounter difficulties in correct needle placement for proper administration of the medication.” ’568 Specification ¶ 4. Such difficulties can be especially significant when medication is delivered via a subcutaneous infusion set. *Id.* In resolving these and other problems, the Appellant’s device allows patients to properly inject a needle for proper placement of an infusion set on a patient. *Id.*

Therefore, Independent Claim 55 (together with its Dependent Claims 57 and 60) and Independent Claim 66 (together with its Dependent Claims 70, 71, and 72) positively recite an injector device assembly having “an infusion set” that includes at least “a housing and a hollow cannula.” Unlike Miskinyar’s preloaded syringe, an infusion set is removably positioned from, and contained within, the injector device housing. The plain and ordinary meaning of an infusion set is supported by the ’568 Specification. In particular, the infusion set includes its own separable “housing for stable affixation thereof to the skin of the patient.” ’568 Specification ¶ 39. The infusion set “receives medication via infusion tubing” (*Id.* at ¶ 39) and permits “medication delivery through the cannula 26 to the patient.” *Id.*; see also ¶ 6 (“After priming and placement of the infusion set the injector device is removed and delivery of medication is initiated”).

Accordingly, Miskinyar does not teach the claimed infusion set, and the rejection of Claims 55, 57, 60, 66, and 70–72 should be reversed.

(ii) Miskinyar does not teach a “cover removably connected to a front end portion of said housing and ... receiving a part of said infusion set”

The Examiner very briefly concludes that Miskinyar teaches “a cover (38).” But that conclusory statement is incomplete. Simply put, Miskinyar describes nothing more than a cover 38, and the Examiner stops far short of describing how the cover anticipates the cover of Independent Claim 66 or its Dependent Claims 70–72. It does not. As shown in FIG. 2 of Miskinyar, the cover 38 covers the button 33 on the opposite end of the needle. In addition, the “cover 62” referred to by the Examiner is actually the bottom wall of the housing and not a cover at all. (col. 3, ll. 8-9.)

Independent Claim 66 specifically states that the cover is connected to the “front end portion” of the housing. Also, the claim positively recites an infusion set, and then recites a cover “receiving a part of said infusion set.” Since Miskinyar lacks an infusion set as shown above in Part (8)(a)(i), it cannot anticipate Independent Claim 66 or Dependent Claims 70, 71, and 72. Furthermore, the Examiner’s interpretation of a “cover” is not reasonable in view of Applicants’ specification, which explains that the cover receives a part of the infusion set to provide “a ready to use injector device” (’568 Specification ¶ 41) and to provide a “sterile sealed, single use assembly” so that “no further packaging is required leading to substantial cost reductions” (’568 Specification ¶ 7).

Separately, Dependent Claim 60 (which depends from Independent Claim 55) and Dependent Claim 72 (which depends from Independent Claim 66) recite a removable cover having a hollow portion for covering said infusion set receiving a part of an insertion needle when said plunger is in said advanced position. In contrast, the so-called cover 38 of Miskinyar actually encloses the button 33 on the opposite side of the device from the hypodermic needle 22. See Miskinyar Fig. 7 (Showing cover enclosing button 33 and opposite needle 22); see also Miskinyar, col. 3, ll. 18–20 (The Miskinyar cover 38 encases the button at the back of the housing 10 and extends to “about the mid-portion of the housing 10”). As such, Miskinyar’s “cover” does not *cover* an opening in the housing front end, insertion needle, or infusion set.

Accordingly, Miskinyar does not teach the front-end cover for receiving a part of the claimed infusion set, and the rejection of Claims 66 and 70–72 should be reversed.

(iii) Miskinyar does not teach a “housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger”

The Examiner’s position is that a “button 33” of Miskinyar is a “device housing being manually deformable.” Office Action dated 5/23/2008, at 2. The Examiner is not taking proper account of a point made in the Appellant’s April 23, 2008 Amendment, which clarified that the “manually deformable housing” is deformable “from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger.” Miskinyar does not teach a manually deformable housing as claimed.

First, the disposable syringe housing 10 of Miskinyar is not designed to be manually deformable. See Miskinyar, col. 2, l. 35. In fact, nowhere does Miskinyar even hint at the disposable syringe housing 10 being designed to be deformable.

Second, because the disposable syringe housing 10 is rigid, the Examiner erroneously attempts to combine a button 33 with the housing 10 to result in the claimed “device housing being manually deformable.” Specifically, the Examiner asserts that: “The button of Miskinyar is *considered* part of the housing because it covers the top of the device.” Office Action dated 5/23/2008, at 3 (emphasis added).

In other words, the Examiner’s position is that the housing 10 and button 33, when combined, equate to a manually deformable housing as claimed in the present application. However, this interpretation of housing 10 to constitute a button 33 ignores the plain and ordinary meaning of the term “housing.” Furthermore, this interpretation is inconsistent with Miskinyar’s own description of its housing as a cylindrical member that encases an operating mechanism. See Miskinyar, col. 2, ll. 34–37. Moreover, Miskinyar never describes the button 33 as “part of the housing” – as the Examiner assumes. Rather, Miskinyar distinguishes between a button 33 and a housing 10: “The button 33 is enclosed within a protective cover 38 which seats against an annular rim 39 about the mid-portion of the housing 10.” Miskinyar, col. 3, ll. 18–20.

Third, both the button 33 and disposable syringe housing 10 of Miskinyar retain their respective shapes, which makes Miskinyar patentably distinct from the claimed invention. The Examiner's interpretation that the syringe of Miskinyar teaches a "manually deformable (button 33) to release the plunger" lacks support from Miskinyar, on the one hand, and ignores the Appellant's claim language on the other. *In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007) ("A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.").

For instance, Independent Claim 55 specifically states the device housing is manually deformable "from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." Contrary to the Examiner's interpretation, the claim term should be viewed in accordance with its plain meaning as well as Appellant's specification. As explained in the specification, a benefit of this claim element is to provide a ready-to-use injector device and subcutaneous infusion set. See '568 Specification ¶ 41. Because the housing of the injector device is molded from a manually deformable plastics material, the injector device will effectively simplify the placement of an infusion set as the assembly as delivered from the factory. *Id.* Furthermore, the time required for the placement of an infusion set is reduced by placing the injector device on the skin of the patient (*Id.* at ¶ 42) and releasing the plunger 30 simply "by pressing manually on diametrically opposed outside areas of the device housing 28 to deform the housing 28 and thereby effect release of the trigger arms 38." *Id.* at ¶ 43.

Dependent Claims 57 and 60 incorporate by reference the foregoing elements of Independent Claim 55. Thus, they are not anticipated by Miskinyar for the reasons given in support of Independent Claim 55. In addition, Dependent Claim 57 recites that the housing has a generally planar surface at the forward end in order to facilitate placement of the injector device housing against the patient's skin.

Separately, Dependent Claim 60 depends from Independent Claim 55. Thus, Dependent Claim 60 incorporates a "device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger," which was discussed above in this Part (8)(a)(iii). In addition, Dependent Claim 60 recites a removable cover that covers the end of the housing, the

infusion set, and the insertion needle. The cover of Dependent Claim 60 was discussed above in Part (8)(a)(ii), which discussion is incorporated by reference.

Similarly, Dependent Claim 72 recites a removable cover that covers the end of the housing, the infusion set, and the insertion needle. This cover is not taught in Miskinyar. See *supra* Part (8)(a)(ii); compare '568 Specification ¶ 67 with Miskinyar Fig. 6 and col. 3, ll. 18–20 (cover 38 encases the button at one end and “seats against an annular rim 39 about the mid-portion of the housing 10”).

Accordingly, Miskinyar does not teach at least the claimed “housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger,” and the rejection of Claims 55, 57, 60, and 72 should be reversed.

(iv) Miskinyar does not teach a “housing being manually deformable ... to effect release of said plunger”

Dependent Claims 70 and 71 depend from Independent Claim 66. Dependent Claim 70 adds the feature that the housing is manually deformable, which was discussed above in Part (8)(a)(iii) as patentably distinct from the rigid disposable syringe housing 10 disclosed in Miskinyar.

Dependent Claim 71, which depend from Claim 70, further recites that the housing has manual engagement areas. In order to deform the housing manually and release the plunger, a pair of manual engagement areas 303 are shown in diametrically opposed positions on the housing. Pressing radially inward on the manual engagement areas releases deform the housing, releases trigger arms 38 that had locked the plunger into a retracted position, and thereby release the plunger. This is shown at least in '568 Specification Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b, and is discussed throughout the '568 Specification, including at least in ¶¶ 43, 55, 68, 72. Miskinyar's single actuation “button 33” is structurally and functionally different from the manual engagement areas of Dependent Claim 71.

Accordingly, Miskinyar does not teach the claimed “housing being manually deformable ... to effect release of said plunger,” and the rejection of Dependent Claims 70 and 71 should be reversed.

- (b) **The rejection of claims 55–57, 60–64, 66, and 69–72, as anticipated by Safabash should be reversed, because Safabash does not teach either a “housing being manually deformable ... to effect release of said plunger” or a “cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing”**

Independent Claims 55, 56, 61, and 66, and Dependent Claims 56–57, 60–64, and 69–72, are rejected as anticipated by Safabash et al., U.S. Patent No. 6,293,925 (“Safabash”), under 35 U.S.C. § 102(e). Like Miskinyar, Safabash does not teach every element recited in these claims and, therefore, cannot anticipate the claimed inventions.

- (i) **Safabash does not teach a “housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger”**

Based on Safabash, the Examiner attempts to equate the insertion device 500 and the release/trigger buttons 508, 510, 512 of that reference with the Appellant’s “housing being manually deformable.” Plainly stated, the Examiner must acknowledge that Safabash says nothing about a “housing being manually deformable.” Indeed, the Examiner never cites to the housing at all. Office Action dated 5/23/2008, at 2 (citing to reference numeral 500). And the Examiner never identifies (because she cannot) a manually deformable *housing*. Instead, the Examiner cites to a release button 508 and two trigger buttons 510, 512. Office Action dated 5/23/2008, at 3 (a “manually deformable housing (508, 510, 512).”). But these citations show that the Examiner is misreading Safabash:

- Safabash does not identify its “housing” by reference numeral 500, which numeral is used to identify the insertion device as a whole. Safabash, col. 15, ll. 65–66 (“Figs. 35–40g illustrate an insertion device 500 in accordance with a second embodiment of the present invention.”).
- To the contrary, Safabash describes its barrel to be the device housing: “The insertion device 500 includes a barrel 502 (or device housing).... As shown in Fig. 35, the barrel 502 performs as a housing.” Safabash, col. 15, l. 67 through col. 16, l. 1.

- Moreover, reference numerals 508, 510, 512 in Safabash do not correspond to the barrel 502 (i.e., the device housing). Rather, they correspond to “a release button 508, and dual spring triggers 510 and 512.” Safabash, col. 16, ll. 4–5.

Safabash’s description of the barrel 502 as the device housing is consistent with the plain and ordinary meaning of the term housing. Safabash never describes the barrel 502 as flexible, and the Examiner cannot find one passage in Safabash even remotely suggesting that the barrel 502 is intended to be manually deformable. Instead, the Examiner places too little emphasis on the structure in Safabash and how the structure releases the plunger, while the Examiner places too much emphasis on the mere end result without regard to the claimed structure in Appellant’s application. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”) (emphasis in original). But the barrel and release/trigger buttons in Safabash are separate, distinct structures. The barrel is not a button, the button is not a barrel, and only the barrel is the “housing” according to the very teachings of Safabash and the plain meaning of the term.

Perhaps the Examiner’s flawed construction began with the Examiner’s earlier citation to Funderburk et al., U.S. Patent No. 6,093,172 (the parent of Safabash) and has been perpetuated ever since. Much like Safabash, the Funderburk patent described the injector as including a “cylindrical forward barrel 28 having a plunger 30 mounted therein.” Funderburk, col. 5, ll. 45–46. Also, Funderburk described how “[a] trigger button of the actuator assembly 34 is adapted for fingertip depression to release the plunger 30.” *Id.* at col. 5, ll. 56–58. From this, the Examiner mistakenly assumed that, “[w]hen element 38 is depressed, the housing is *considered* to be ‘deformed’” to release the plunger 30. Office Action dated 8/1/2006 (emphasis added). The Examiner is not accurately reviewing how the art actually work and is not then or now giving the amended claim element a reasonable construction consistent with the specification. *In re Baker Hughes Incorporated*, 215 F.3d 1297, 1303 (Fed. Cir. 2000) (“We therefore conclude that the Board adopted a construction of the claim beyond that which was reasonable in light of the totality of the written description.”); see also *supra* Parts (8)(a)(iii)–(iv) (discussing the specification support for the manually deformable housing).

The Examiner has failed to cure this deficiency by citing to the continuation of Funderburk, i.e., Safabash. On January 23, 2008, the Examiner made the unsupported assumption that the release button 508 of Safabash is a “manually deformable housing” that releases a plunger. Office Action dated 1/23/2008, at 3. Then, on May 23, 2008, the Examiner broadened her assumption by declaring that it was the release button 508 and dual spring triggers 510, 512 that formed the manually deformable housing. Office Action dated 5/23/2008, at 3. However, the depression of a release button 508 and triggers 510, 512 does not constitute the housing of the claimed inventions without ignoring the plain meaning of Appellant’s claim, specification, and express claim amendment reciting that the housing was “manually deformable from a first geometrical housing configuration to a second geometrical housing configuration *to effect release of said plunger*.” As claimed, the housing itself changes geometrical configuration such that the plunger is released.

It is unreasonable for the Examiner to ignore any interpretive guidance afforded by the specification, as well as the clarifying claim amendment of April 23, 2008. Accordingly, Safabash does not teach the claimed “housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger,” and the rejection of Independent Claims 55, 56, 61 and their Dependent Claims 57, 60, or 62–64, should be reversed.

(ii) Safabash does not teach a “housing being manually deformable ... to effect release of said plunger”

Dependent Claims 70 and 71, which depend from Independent Claim 66, add the feature that the housing is manually deformable. Dependent Claim 71 further recites manual engagement areas 303 for deforming the housing manually to release trigger arms 38 that had locked the plunger into a retracted position, and thereby to release the plunger. See ’568 Specification Figures 9–10, 19, 20a–20e, 21a–21b, and 22a–22b and Specification ¶¶ 43, 55, 68, 72. The release and trigger buttons 508, 510, 512 in Safabash are structurally and functionally different from the manually deformable housing of Claim 71 or the manual engagement areas of Dependent Claim 71. See, e.g., *supra* Part (8)(a)(iv).

Accordingly, Safabash does not teach the claimed “housing being manually deformable ... to effect release of said plunger,” and the rejection of Dependent Claims 70 and 71 should be reversed.

(iii) Safabash does not teach the claimed “cover”

The Examiner stated in the January 23, 2008 rejection that she interpreted the claimed “cover” to read on reference numeral 414 of Safabash. By this, the Examiner clearly meant that she interpreted the claimed cover to encompass a “piercing member guard 414 (or *needle guard*)” that seats “*in*” a cavity 514 of a carrier body 504 that is positioned inside the housing barrel 502. Safabash, col. 19, ll. 27–30 (emphasis added). The Examiner reiterated this interpretation in the final rejection: “As to Safabash, cover 414 clearly covers the entire *needle*.” Office Action dated 5/23/2008, at 3 (emphasis added).

However, the Examiner may not disregard the claim language when rendering a patentability determination. In contrast to the needle cover of Safabash that seats inside the carrier body to cover the entire needle and not the housing, the claimed inventions describe a different structural arrangement where the cover is secured to the **housing**: “a cover member removably secured to said device housing, said cover member *covering an end of said device housing*.” See ’568 Independent Claims 55, 56, 60, 61, and 66 (emphasis added). Moreover, the structure disclosed in the specification corresponds to such claim language: a cover 142 *covers* the bottom end of the injector device 110.” ’568 Specification ¶ 51 (emphasis added); ¶ 55 (The lower cover 142 is “connected to the device housing 128.”); ¶ 57 (The bottom cover 142 is sealed “to the device housing 128”); see also Figs. 6–12. This structural arrangement has several advantages. It allows the cover to receive the infusion set, to provide “a ready to use injector device” (’568 Specification ¶ 41), and to provide a “sterile sealed, single use assembly” so that “no further packaging is required leading to substantial cost reductions” (’568 Specification ¶ 7).

Separately, Dependent Claim 60 (which depends from Independent Claim 55) further recites a removable cover having a hollow portion for “covering said infusion set.” But the needle guard 414 of Safabash does not cover the infusion set. See Safabash Fig. 40a.

Rather, the needle guard 414 engages only the needle hub 408. Safabash, col. 17, ll. 13–14; col. 19, ll. 27–28.

Accordingly, Safabash does not teach the claimed “cover member removably secured to said device housing, said cover member covering an end of said device housing.” The rejection of Claims 55–57, 60, 61–64, 66, and 69–72 should be reversed.

(c) The rejection of claims 58 and 59 as rendered obvious by Safabash in view of Teeple should be reversed, because those references are not properly combined and all limitations are not taught even if combined

Claims 58 and 59 are rejected as obvious over Safabash in view of Teeple, Jr., U.S. Patent No. 6,158,437 (“Teeple”), under 35 U.S.C. § 103(a). Obviousness cannot be established by merely combining prior art to produce a claimed invention. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (The Examiner must consider (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness.). And when properly combined, the references must teach all elements of the claimed invention.

In the instant case, the Examiner admits that Safabash (an insertion device) does not disclose or suggest “indicia,” but then cites one line from Teeple (mixing of anesthetic drugs) in support of the assumption that Teeple teaches this missing element: “Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device.” Office Action dated 5/23/2008, at 3. Appellant traverses this rejection on at least two grounds.

First, the decision to combine references must be a thorough, searching, and conscientious effort. Instead of wholesale rejecting the use of “teaching, suggestion, or motivation” (“TSM”) as a factor in the obviousness analysis, the Supreme Court recently recognized that a showing of TSM could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

[The TSM test] captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be

important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.

KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741 (2007).

Here, the Examiner combined Safabash with Teeple. However, the subject matters of those patents are neither common nor analogous. While Safabash relates to an insertion device, Teeple involves the mixing of drug solutions for anesthesia. These are dissimilar subjects, involve different subclasses, and are too distinct to be combined. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (“We conclude that the references on which the Board relied were improperly combined. Accordingly, the Board erred in holding the claims unpatentable under section 103.”); *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention.”); see also *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (“Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.”).

Second, the references, alone or in combination, must disclose each and every element of the claims. But Independent Claim 58 recites many limitations that are not disclosed in Safabash. To name a few, Safabash does not teach a cover for “*covering an end of said device housing*,” but instead merely describes a needle guard 414 that seats inside a cavity of the carrier body. See *supra* Part (8)(b)(iii). Also, Safabash does not teach the manually deformable housing without ignoring the clarification that was added by amendment, i.e., that the housing is manually deformable from a “first geometrical housing configuration to a second geometrical housing configuration to effect the release of said plunger.” See *supra* Part (8)(b)(i).

Moreover, the Examiner admits Safabash does not teach the “indicia” but, with a broad brush, suggests that Teeple provides the missing element. However, the Examiner is taking Teeple out of context. That reference related to shelf life of anesthetic drugs that

break down over time when stored in vials. See Teeple, col. 18, ll. 19–28. Also, the Examiner’s truncated reading of the claim limitation reads out of the claim the recited indicia on the “cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member.” The Examiner does not explain how the bar codes for tracking expired anesthetic drugs would assure “sterile conditions of the infusion set prior to releasing the cover member.” This is not taught, described, or even remotely suggested by Teeple.

Separately, Dependent Claim 59, which depends from Independent Claim 58, further recites that the plunger 30, 130, 230, 330 is in an advanced position prior to first-time removal of the cover 142, 342. In contrast, the user of Safabash “presses against the piercing member guard 414 to move the carrier body 504 from the advance position to the retracted position.” Safabash, col. 19, ll. 36–38; see also Safabash Fig. 40c and col. 19, ll. 32–34 (“It is preferred that the piercing member guard 414 is not removed at this point”).

Accordingly, Safabash in view of Teeple does not teach the claimed invention of Independent Claim 58 or its Dependent Claim 59, and the Examiner’s rejections should be reversed.

(d) Claims 65 and 73 were not properly rejected

Dependent Claim 65 is neither rejected nor objected to. Dependent Claim 65 should be allowed because it depends from an allowed base claim, i.e., Dependent Claim 42. Also, this is not a proper “examination” of Dependent Claim 65. Cf. *Ex parte Gambogi*, 62 U.S.P.Q.2d 1209, 1212 (Bd. Pat. App. & Int. 2001) (“We recommend that in entering any new rejection in the application on appeal that the examiner adopt the practice set out in § 706.02(j) of the *Manual of Patent Examining Procedure* which contains a discussion of what an examiner should set forth in an Office action when making a rejection under 35 U.S.C. § 103(a). Moreover, we additionally recommend that the examiner use the practice set out in *Ex parte Braeken*, i.e., reproducing the claim with reference therein to the column and line of a relevant prior art reference.”) (citation omitted).

Dependent Claim 73, which depends from Independent Claim 55, stands rejected. However, the Examiner never provided a basis for the rejection, and rejected the claim

without reading the claim on any reference or even citing a reference in reaching the rejection. First, the Examiner has not established a prima facie case – or any case – of obviousness regarding Dependent Claim 73. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (“The examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability.”); see also cf. *Ex parte Rozzi*, 63 U.S.P.Q.2d 1196, 1200 (Bd. Pat. App. & Int. 2002) (“One major difficulty with the examiner’s rejection is that he has failed to make a finding with respect to a difference, if any, between the subject matter of claim 1 and [a reference].”). Second, it is an improper rejection to leave it to the applicant or the board to speculate as to why the claim was rejected. Cf. *Ex parte Gambogi*, 62 U.S.P.Q.2d at 1212 (“In this case, however, the examiner has not told applicants or the board what the prior art would have meant to a person skilled in the art. Moreover, the examiner has not referred to specific portions of each of the references. Thus, both applicants and the board have to speculate.”).


Accordingly, Dependent Claim 65 was not rejected, depends from an allowed base claim, and similarly should be allowed. Dependent Claim 73 was not properly rejected, construed, or compared to any prior art reference, and therefore the rejection should be reversed.

(9) CONCLUSION

The Application appears to be in order for allowance, both as to form and in view of the prior art. Accordingly, all rejections applied by the Examiner should be **REVERSED** and claims 55–66 and 69–73 allowed.

Respectfully submitted,

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(10) APPENDIX A – CLAIMS PRESENTED APRIL 23, 2008

Claims 1-39 (Cancelled)

40. An injector device used for transcutaneously placing an insertion needle of a medical device through the skin of a patient, said injector device comprising:

a molded device housing,

a molded plunger for inserting said medical device movably received within the device housing for movement between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable to effect release of said plunger,

a drive including a spring for urging the plunger from the retracted position towards the advanced position,

wherein the drive comprises a plurality of individual flexible plastics members, each member being connected with the plunger and with the device housing, said plastics members forming said spring, and

wherein said insertion needle is hollow and has a lateral opening near said plunger.

41. The injector device of claim 40, including manual engagement areas for the manual deformation of said housing to effect said release of said plunger.

42. The injector device of claim 41, said manual engagement areas being diametrically opposed on said housing and being peripherally offset with respect to said lock.

43. The injector device of claim 42, said manual engagement areas being of fingertip size.

Claims 44-49 Cancelled

50. The injector device of claim 40, wherein said device housing has a forward end defining a generally planar surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin.

51. An injector device used for transcutaneously placing an insertion needle of a medical device through the skin of a patient, said injector device comprising:

a molded device housing,

a molded plunger for inserting said medical device movably received within the device housing for movement between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable to effect release of said plunger,

a drive including a spring for urging the plunger from the retracted position towards the advanced position,

wherein the drive comprises a plurality of individual flexible plastics members, each member being connected with the plunger and with the device housing, said plastics members forming said spring, and

wherein said medical device comprises a tubing, said injector device housing including a space for accommodating said tubing.

52. The injector device of claim 51, each strip being essentially planar and non-deformed in the advanced position of the plunger.

53. An injector device for a medical device, comprising:

a molded device housing;

a molded plunger for inserting said medical device movably received within the device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable to effect release of said plunger; and

a drive including a spring for urging the plunger from the retracted position towards the advanced position;

wherein the drive comprises a plurality of individual flexible plastics members, said plastics members forming said spring, each member being connected with the plunger and with the device housing, and each flexible plastics member is formed as a strip, the injection device including at least two such strips, said two

strips extending in a common plane around a respective part of said periphery of said plunger, and two further strips extending in a second plane around a respective part of said periphery, in said advanced position of said plunger.

54. The injector device of claim 53, said plunger having a recess for accommodating said medical device.

55. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula,

a molded device housing,

a cover member removably secured to said device housing, said cover member covering an end of said device housing,

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger, and

a drive for urging said plunger from the retracted position towards said advanced position.

56. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger; and

a drive for urging said plunger from the retracted position towards said advanced position;

wherein said device housing includes a space for accommodating a tubing that forms part of said infusion set for delivery of medication to said hollow cannula.

57. The injector device assembly of claim 55, wherein the device housing has a forward end defining a generally planar surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin.

58. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger;

a drive for urging said plunger from the retracted position towards said advanced position; and

indicia relating to the shelf life of said assembly on said cover member, and wherein the releasable cover member assures sterile conditions of the infusion set prior to releasing the cover member.

59. The injector device assembly of claim 58, said plunger being in said advanced position prior to first time removal of said at least one cover member.

60. The injector device assembly of claim 55, wherein a removable cover covering said infusion set includes a hollow portion for receiving a part of an insertion needle when said plunger is in said advanced position.

61. An injector device assembly, comprising:

an infusion set including a housing and a hollow cannula;

a molded device housing;

a cover member removably secured to said device housing, said cover member covering an end of said device housing;

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position;

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger; and

a drive for urging said plunger from the retracted position towards said advanced position, said plunger having an insertion needle secured thereto by a stable connection preventing loss of said insertion needle during use of said injector device, said insertion needle extending through said cannula with the cannula oriented for transcutaneous placement upon movement of the plunger from the retracted position to the advanced position, said insertion needle secured to said plunger being removable from said cannula while maintaining the transcutaneous placement of the cannula.

62. The injector device assembly of claim 61, said insertion needle being in frictional engagement with said infusion set.

63. The injector device assembly of claim 61, wherein the insertion needle is secured to said plunger by press-fit.

64. The injector device assembly of claim 61, wherein the insertion needle is hollow and has an entry port and an exit port.

65. The injector device of claim 42, said manual engagement areas being diametrically opposed on said housing and being peripherally offset with respect to said lock by about 90°.

66. An injector device assembly comprising:

an infusion set including at least a housing and a hollow cannula,

a molded device housing receiving at least a part of said infusion set, said part of said infusion set positioned removably from and within said device housing;

a molded plunger movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position,
a drive including a spring for urging the plunger from the retracted position towards the advanced position,
a cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing, said cover receiving a part of said infusion set.

67. An injector device assembly comprising:

an infusion set including at least a housing and a hollow cannula,
a molded device housing receiving at least a part of said infusion set,
a molded plunger movably received within said device housing for transcutaneous placement of said hollow cannula by movement of said plunger between an advanced position and a retracted position,
a lock for releasably locking said plunger in said retracted position,
a drive including a spring for urging the plunger from the retracted position towards the advanced position,
a cover removably connected to a front end portion of said housing and covering an opening defined in the front end portion of said housing, said cover receiving a part of said infusion set,
wherein said drive comprises a plurality of individual flexible plastics members, each member connected with the plunger and with the device housing.

68. The injector device assembly of claim 67, wherein each of said flexible members extend in a space between the plunger and the device housing.

69. The injector device assembly of claim 66, further comprising a medical insertion needle substantially non-detachably attached to said plunger, said medical insertion needle extending through said cannula.

70. The injector device assembly of claim 66, wherein said device housing is manually deformable to effect release of said plunger.

71. The injector device assembly of claim 70, wherein said molded device housing comprises manual engagement areas.

72. The injector device assembly of claim 66, wherein said cover comprises a hollow portion.

73. The injector device assembly of claim 55, wherein said housing comprises a pair of manual engagement areas, said manual engagement areas being pressed radially inwardly in said second geometrical configuration.

(11) APPENDIX B – RELATED PROCEEDINGS

On August 26, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 10/813,214. On October 3, 2008, a Notice of Appeal was filed in United States Patent Application Serial No. 11/031,635. Appellant identifies these as Related Proceedings pursuant to 37 CFR 41.37(c)(1)(ii). To date, there is no decision for inclusion in this Appeal Brief pursuant to 37 CFR 41.37(c)(1)(x).